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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/817,318	03/26/2001	Susana Salceda	DEX-0199	1254

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EXAMINER
DAVIS, MINH TAM B

ART UNIT	PAPER NUMBER
1642	6

DATE MAILED: 02/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application No.	Applicant(s)	
	09/817,318	SALCEDA ET AL.	
	Examin r	Art Unit	
	MINH-TAM DAVIS	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspond nce address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 July 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-25* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-25* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Groups 1-20. Claims 1-6, 9, 23 , drawn to a polynucleotide of SEQ ID Nos:1-20, an antisense, a vector, a host cell, a method for producing mammary gland cancer specific or MSG polypeptide, a method for producing a cell expressing a MSG polypeptide, classified in class, subclass. Each polynucleotide constitutes a single invention, and not a species. Applicant is required to elect a single invention.

Groups 21-40. Claims 7, 9, 23, drawn to a polypeptide encoded by a polynucleotide of SEQ ID Nos:1-20, classified in class, subclass . Each polypeptide encoded by a polynucleotide constitutes a single invention, and not a species. Applicant is required to elect a single invention.

Groups 41-60. Claim 8, drawn to an antibody specific for a polypeptide encoded by a polynucleotide of SEQ ID Nos:1-20, classified in class, subclass . Each antibody specific for a polypeptide encoded by a polynucleotide constitutes a single invention, and not a species. Applicant is required to elect a single invention.

Groups 61-80. Claim 10, drawn to a method for diagnosis of cancer, comprising detecting the level of a MSG polynucleotide of SEQ ID Nos: 1-20, classified in class, subclass. Each method detecting a polynucleotide

constitutes a single invention, and not a species. Applicant is required to elect a single invention.

Groups 81-100. Claim 10, drawn to a method for diagnosis of cancer, comprising detecting the level of a polypeptide encoded by a MSG polynucleotide of SEQ ID Nos: 1-20, classified in class, subclass. Each method detecting a polypeptide encoded by a polynucleotide constitutes a single invention, and not a species. Applicant is required to elect a single invention.

Groups 101-120. Claims 11, 13, drawn to a method for diagnosis of metastasis or onset of mammary gland cancer, comprising detecting the level of a MSG polynucleotide of SEQ ID Nos: 1-20, classified in class, subclass. Each method detecting a polynucleotide constitutes a single invention, and not a species. Applicant is required to elect a single invention.

Groups 121-140. Claims 11, 13, drawn to a method for diagnosis of metastasis or onset of mammary gland cancer, comprising detecting the level of a polypeptide encoded by a MSG polynucleotide of SEQ ID Nos: 1-20, classified in class, subclass. Each method detecting a polypeptide encoded by a polynucleotide constitutes a single invention, and not a species. Applicant is required to elect a single invention.

Groups 141-160. Claims 12, 14, drawn to a method for staging mammary gland cancer, or monitoring changes in stages of mammary gland cancer, comprising detecting the level of a MSG polynucleotide of SEQ ID Nos: 1-20, classified in class, subclass. Each method detecting a polynucleotide

constitutes a single invention, and not a species. Applicant is required to elect a single invention.

Groups 161-180. Claims 12, 14, drawn to a method for staging mammary gland cancer, or monitoring changes in stages of mammary gland cancer, comprising detecting the level of a polypeptide encoded by a MSG polynucleotide of SEQ ID Nos: 1-20, classified in class, subclass. Each method detecting a polypeptide encoded by a polynucleotide constitutes a single invention, and not a species. Applicant is required to elect a single invention.

Groups 181-200. Claim 15, drawn to a method for identifying compounds that bind to a MSG polynucleotide of SEQ ID Nos: 1-20, classified in class, subclass. Each method detecting compounds that bind to a polynucleotide constitutes a single invention, and not a species. Applicant is required to elect a single invention.

Groups 201-220. Claims 15, 20, drawn to a method for identifying compounds that bind to or antagonize or agonize a polypeptide encoded by a MSG polynucleotide of SEQ ID Nos: 1-20, classified in class, subclass. Each method detecting compounds that bind to or antagonize or agonize a polypeptide encoded by a polynucleotide constitutes a single invention, and not a species. Applicant is required to elect a single invention.

Groups 221-240. Claims 16-17, drawn to a method of imaging mammary gland cancer in a patient, comprising administering to the patient an antibody

specific for a polypeptide encoded by a polynucleotide of SEQ ID Nos:1-20, classified in class, subclass . Each method using an antibody specific for a polypeptide encoded by a polynucleotide constitutes a single invention, and not a species. Applicant is required to elect a single invention.

Groups 241-260. Claims 18-19, drawn to a method for treating mammary gland cancer in a patient, comprising administering to the patient an antibody specific for a polypeptide encoded by a polynucleotide of SEQ ID Nos:1-20, classified in class, subclass . Each method using an antibody specific for a polypeptide encoded by a polynucleotide constitutes a single invention, and not a species. Applicant is required to elect a single invention.

Groups 261-280. Claims 21, 22, drawn to an agonist or antagonist of a polypeptide encoded by a polynucleotide of SEQ ID Nos:1-20, classified in class, subclass . Each agonist or antagonist of a polypeptide encoded by a polynucleotide constitutes a single invention, and not a species. Applicant is required to elect a single invention.

Groups 281-300. Claims 24-25, drawn to a method for inducing an immune response or treating mammary gland cancer, comprising administering a MSG polynucleotide of SEQ ID Nos: 1-20, classified in class, subclass. Each method using a polynucleotide constitutes a single invention, and not a species. Applicant is required to elect a single invention.

Groups 301-320. Claims 24-25, drawn to a method for inducing an immune response or treating mammary gland cancer, comprising administering a polypeptide encoded by a MSG polynucleotide of SEQ ID Nos: 1-20, classified in class, subclass. Each method using a polypeptide encoded by a polynucleotide constitutes a single invention, and not a species. Applicant is required to elect a single invention.

In addition, upon the election of any of groups 101-140, further election of the following patentably distinct species of the claimed invention is required:

Metastasis or onset of metastasis.

Upon the election of any of groups 141-180, further election of the following patentably distinct species of the claimed invention is required:

Staging or detection of change in stage of mammary gland cancer.

Upon the election of any of groups 201-220, further election of the following patentably distinct species of the claimed invention is required:

1) Compounds that bind to a MSG polypeptide or 2) compounds that antagonize a MSG polypeptide or 3) compounds that agonize a MSG polypeptide, wherein compounds bind to a MSG polypeptide are generic to compounds that antagonize a MSG polypeptide and compounds that agonize a MSG polypeptide.

Upon the election of any of groups 261-280, further election of the following patentably distinct species of the claimed invention is required:

Agonist or antagonist.

The inventions are distinct, each from each other because of the following reasons:

Inventions (1-60, 261-280) and (61-260, 281-320) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. 806.05 (h). In this instant case, a polypeptide could be used for several purposes, e.g. for biochemical assay, for making antibodies, and for making an affinity column to purify its antibodies; a DNA sequence could be used for the detection of similar DNA or RNA sequences, for making an expression vector, and for producing its encoded protein; and an antibody could be used for immunoassay, for purification of its antigen, and for detection of diseases.

The products of groups 1-60, 261-280 are patentably distinct, because they are drawn to entirely different biochemicals , having different structures, biological properties and activities .

The methods of groups 61-260, 281-320 are distinct from each other because they differ at least in objectives, method steps, reagents and/or dosages, and/or schedules used, response variables and criteria for success.

The sequences of SEQ ID Nos: 1-20 are distinct because they are structurally distinct.

The species detecting metastasis or monitoring onset of metastasis are distinct because they require different method steps, wherein monitoring onset of metastasis involves determining the level of MSG periodically because the presence of metastasis.

The species staging or detection of change in stage of mammary gland cancer are distinct, because they have different objectives.

The species compounds that antagonize a MSG polypeptide and compounds that agonize a MSG polypeptide are distinct, because they have opposite properties.

Because these inventions are distinct for the reason given above and have acquired a separate status in the art, and because the searches for the groups are not co-extensive, restriction for examination purposes as indicated is proper.

Applicants are required under 35 USC 121 to elect a single disclosed group for prosecution on the merits to which the claims shall be restricted. Applicant is further advised that if Applicant elects a group having species requirement, a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over

the prior art, the evidence or admission may be used in a rejection under 35 USC 103 of the other invention.

Applicants are reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendement of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. 1.48(b) and by the fee required under 37 C.F.R. 1.17(h).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 703-305-2008. The examiner can normally be reached on 9:30AM-4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, ANTHONY CAPUTA can be reached on 703-308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0916.

MINH TAM DAVIS

February 11, 2002

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